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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/060,188 04/14/98 BEHAN

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EXAMINER

HM12/1010

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SAN DIEGO CA 92121

BASI, N	
ART UNIT	PAPER NUMBER

1646

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/060188

Applicant(s)

Behan et al

Examiner

Nimal S. Basi

Group Art Unit

1846

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. ^{10/9}

- Amended*
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/19/01
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 33, 34, 39, 40, 45-68 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 33, 34, 39, 40, 45-68 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is: ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received:
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 25
- ☐ Interview Summary, PTO-413
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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DETAILED ACTION

1. Amendments filed 7/19/01 has been entered.

2. *Election/Restriction*

Applicant's election without traverse of Group I, species 116 encompassing

5 “Location:ventromedial hypothalamus, Correlated with Physiological Function: food intake”, in
Paper No. 26 (7/19/01). Non-elected species have been canceled. Claims 33-34, 38-40 and 45-68
are pending

Claim Rejection, 35 U.S.C. 112

10 3. Claims 33-34, 39-40 and 45-68 are rejected under 35 U.S.C. 112, second paragraph, as
being indefinite for failing to particularly point out and distinctly claim the subject matter which
applicant regards as the invention.

Claims 33 and 39 contain an improper Markush grouping because the claim does not
contain multiple elements. Further the claim is objected to because it contains a table. The use of
the table in the claim is neither necessary or otherwise found desirable, see 37 C. F.R. 1.58.

15 Applicant must Amend the claim to narrative fashion.

Claim 33 is indefinite because it is not clear what receptor from which tissue source is
correlated with what physiological function. The preamble of the claim states the “the location of
expression of said receptor has been identified from mammalian tissue source and has been
correlated with at least on physiological function in a mammal”, but claim is directed to

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determining the location of expression, tissue source and physiological function. Similarly claim 39 is rejected for the reasons given above.

Claims 67 and 68 are indefinite because it is not clear what is an abnormal physiological function so as to allow the metes and bounds to be determined. For example is sweating an abnormal or normal physiological response. How does the magnitude of the response play a role in determining its abnormality. Therefore abnormal physiological function is not an absolute value in many cases, and without guidance from the specification the metes and bound so the claim cannot be determined.

Claims 34, 40 and 45-66 are rejected for depending on a indefinite base claim and fail to resolve the issues raised above.

New Matter rejection

4. Claims 33 and 39 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants arguments and the Lewis declaration, pertaining to new matter, have been fully considered but not found persuasive. Applicant and the Lewis' disclosure argue that the broad disclosure of the originally filed patent application provides support for the claimed species. Applicants arguments and the Lewis declaration have been fully considered but not found persuasive. Claims recite in the preamble, "wherein a location of expression of said agonist has

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been identified from mammalian tissue source and has been correlated with at least one physiological function in a mammal comprising” and then disclose “Location:ventromedial hypothalamus, Correlated with Physiological Function: food intake”. The afore mentioned limitation does not appear in the original specification. Applicant has not disclosed where the species specifically appears in the specification.

Response to the Applicants Arguments on utility. Applicant, the Lewis Declaration and Watson Declaration generally argue that the orphan receptor can have utility even though the endogenous ligand is not known. Based on Applicants arguments, which in part, pertain to an orphan receptor named 18F, which was determined to be localized in an area of the brain, which is associated with feeding, and that a small molecule candidate compound directly identified by the method of the claimed invention decreased food consumption when administered to animals. Examiner agrees that an orphan receptor when directly correlated with a useful function, such as affecting food intake or a disease state would have a utility in a method for directly identifying its agonist. In contrast, the methods of instant invention are directed to orphan receptors with known ligand or function. The claims do not associate a particular useful function with a specific receptor. In fact claim 33 requires the”determining the location of expression of said receptor in a mammalian tissue source and correlating the expression location of said receptor with at least one mammalian physiological function of interest”. Therefore using an orphan receptor with no disclosed function

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and ligand will be devoid of utility under 35 U.S.C. 101. In contrast using the 18F receptor, even though endogenous ligand is not known, would have utility.

5 ***Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st paragraph***

The following is a quotation of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10 The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15

6. Claims 33-34, 39-40 and 45-68 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

20 A "specific utility" is a utility that is specific to the subject matter claimed, as opposed to a "general utility" that would be applicable to the broad class of the invention. A "substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial

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utilities. A "well established utility" is a utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. A "well established utility" must also be specific and substantial as well as credible.

5 Based on the record, there is not a "well established utility" for the claimed invention.

Applicant has asserted utilities for the specifically claimed invention of claims 33-34, 39-40 and 45-68. For example, the specification at page 31 asserts, "The fundamental insight underlying the present invention is the recognition that it is the constitutively activated form of receptors which can be used to directly identify lead compounds which affect receptor activity",
10 and further states that, "Essentially, the method of this invention provides a means for discovering modulators of receptor function without the need for any knowledge of the endogenous ligand".

 The utilities asserted by Applicant are specific. However, the asserted utilities are not substantial. Because an orphan receptor, does not have, by definition, a corresponding endogenous ligand that is known, the specification nor the art of record disclose the function of orphan receptors, the proteins they modulate and their effects on specific disease states. Similarly,
15 constitutively activated orphan receptors have no known function. Thus the corresponding asserted utilities are essentially methods of identify lead compounds which affect constitutively activated orphan receptor activity, which does not define a "real world" context of use. Therefore identifying compounds that interact with orphan receptors would require or constitute carrying
20 out further research to identify or reasonably confirm a "real world" context of use. Since neither

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the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the claimed method of identifying compounds having activity of inverse agonist or agonist activity, further experimentation is necessary to attribute a utility to constitutively activated orphan receptors and to the compounds that bind the constitutively activated orphan receptors. See *Brenner v. Manson*, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

5. Claims 33-34, 39-40 and 45-68 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Serial Number:09/060,188

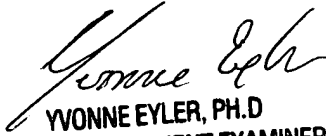
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Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
October 9, 2001


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